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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/578,536 | 03/21/2007 | Sharon M. Wahl | 64868(47992) | 9065 |

46037 7590 12/02/2009

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| EXAMINER | |
|---|---|
| WOLLENBERGER, LOUIS V | |
| ART UNIT | PAPER NUMBER |
| 1635 | |
| MAIL DATE | DELIVERY MODE |
| 12/02/2009 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/578,536 | WAHL ET AL. | |
| | Examiner | Art Unit | |
| | Louis Wollenberger | 1635 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *25 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-11,13-22 and 24-34* is/are pending in the application.

4a) Of the above claim(s) *3-11,14-22 and 24-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/4/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

Applicant's election of Group III, drawn to a method of attenuating infection or transmission of an immunodeficiency virus via a p21 inhibitor that is 2-cyano-3,12-dioxooleana-1,9-dein-28-oic acid, in the reply filed on 8/25/2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicant's amendments to the claims, filed 8/25/2009 with the response to the Restriction, are acknowledged. The status identifiers and amendments make it clear Applicant considers Claims 1, 2, and 13 read on the elected invention. The Examiner agrees.

With entry of the amendment, claims 1-11, 13-22, and 24-34 are pending.

Claims 3-11, 14-22, and 24-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 1, 2, and 13 are examined herein.

### *Claim Objections*

Claim 13 is objected to because of the typo "susceptiple" in line 2. Appropriate correction is required.

### *Specification*

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code at page 13. Deleting the "http://" portion of this web address would be remedial. See MPEP §608.01.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112, second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to methods of attenuating transmission or infection of an immunodeficiency virus in a cell and treating AIDS in an individidual using any derivative of CDDO. One of skill in the art would not know the metes and bounds of the term "derivative thereof" because the specification has not clearly defined how and to what degree a compound can differ from CDDO and still be considered a derivative.

***Claim Rejections - 35 USC § 112, first paragraph (written description)***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Factors to be considered in determining whether there is sufficient evidence of possession include the level of skill and knowledge in the art, complete or partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient.

The claims are drawn to methods of attenuating transmission or infection of an immunodeficiency virus in a cell and treating AIDS in an individidual using any derivative of CDDO.

Thus, the claims are extremely broad, embracing an astronomical number of methods for attenuating any immodeficiency virus, including but not limited to HIV, using any compound that may reasonably be considered to be a derivative of CDDO.

Adequate written description does not exist in the instant application for all these methods. That is, the specification does not adequately allow persons of ordinary skill in the art to recognize that applicant(s) were in possession of the entire genus of CDDO derivatives that will attenuate HIV and all other immunodeficiency viruses or that may be used to treat AIDS in an individual. While the application as filed has adequately described a single triterpenoid, CDDO (pp. 62-63), that would be recognized as having the function required by the claims, species alone would not enable one of skill to predict the structure of any other species within the

genus having these functions. (The structure of di-CDDO, disclosed at page 63, is not disclosed by the specification and not readily identified by a review of the prior art. It is unclear, for example, whether di-CDDO refers to the dicyano analogue or some other CDDO compound.) While CDDO belongs to a recognized class of compounds known in the art as triterpenoids or triterpenes, there is no evidence showing or teaching what portion or group(s) if any, of the triterpenoid or CDDO pentacyclic structure is common to the class of CDDO derivatives that produce the effect required by the claims. Thus, Applicant has not taught a structure common to the genus or numbers of species sufficiently representative of the genus, which the term "derivative thereof" reasonably implies has no structural limits, having the function required by the claims. While one of skill might readily imagine several derivatives of CDDO, one skill could not determine which of these, if any, would have the function required by the claims without resorting to de novo testing, and there is no evidence to show that all or at least a significant and representative fraction of all compounds derived from CDDO will have the function required by the claims. As written then, the claims would pre-empt the future, claiming methods of using compounds that have not been identified and which could only be identified by trial and error screening of candidate compounds.

*Vas-Cath Inc. v. Mahurkar,* 19USPQ2d 1111, clearly states that applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. A disclosure in a parent application that merely renders the later-claimed invention obvious is not sufficient to meet the written description requirement; the disclosure must describe the claimed invention with all its limitations. *See Lockwood* , 107 F.3d at 1572, 41 USPQ2d at 1966. An applicant shows possession of the claimed invention by

describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

MPEP 2163 states the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406. MPEP §2163 states futher a patentee of a biotechnological invention cannot necessarily claim a genus after only describing a limited number of species because there may be unpredictability in the results obtained from species other than those specifically enumerated. A patentee will not be deemed to have invented species sufficient to constitute the genus by virtue of having disclosed a single species when … the evidence indicates ordinary artisans could not predict the operability in the invention of any species other than the one disclosed. *In re Curtis*, 354 F.3d 1347, 1358, 69 USPQ2d 1274, 1282 (Fed. Cir. 2004)."

"…a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion" (Brenner, Comr. Pats. v. Manson, 148 USPQ 689 (U.S. 1966)).

Accordingly, only methods comprising the use of CDDO and its salts meet the written description requirement.

Applicant is reminded that the written description requirement is separate and distinct from the enablement requirement. *In re Barker*, 559 F.2d 588, 194 USPQ 470 (CCPA 1977), cert. denied, 434 U.S. 1064 (1978); *Vas-Cath, Inc.* v. *Mahurkar*, 935 F.2d 1555, 1562, 19 USPQ2d 1111, 1115 (Fed. Cir. 1991).

***Claim Rejections - 35 USC § 112, first paragraph (enablement)***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, and 13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of reducing HIV replication and levels in cells in culture and for reducing viral replication and levels in an individual, does not reasonably provide enablement for methods of attenuating the transmission or infection of HIV using any CDDO derivative, or for methods of attenuating the transmission or infection of any known or yet to be identified immunodeficiency virus using CDDO or any derivative thereof, or for methods of treating AIDS in an individual.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Factors to be considered in a determination of lack of enablement include, but are not limited to:

(A) The breadth of the claims;

(B) The nature of the invention;

(C) The state of the prior art;

(D) The level of one of ordinary skill;

(E) The level of predictability in the art;

(F) The amount of direction provided by the inventor;

(G) The existence of working examples; and

(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

*In re Wands,* 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)

The prior and post-filing art indicates AIDS or acquired immunodeficiency syndrome involves a multitude of abnormal cellular disorders and physiological changes, ranging from opportunistic infections to cancer, that may vary from individual to individual. While the instant application reasonably shows the administration to cells of CDDO before or at the time of infection by HIV reduces HIV replication and levels of detectable virus in cell culture, and while one of skill would reasonably infer these results could be extrapolated to cells in vivo, the specification does not show or reasonably suggest CDDO may be used to treat early or acute stage AIDS, as the term may be understood in the art, or any of the AIDS diseases directly resulting from HIV infection. Rather, the specification more narrowly shows how to use CDDO to inhibit HIV replication in a cell in vitro or in vivo, which may reasonably be construed as a treatment for persons infected with HIV, but not necessarily as a treatment for persons suffering from AIDS, including advance AIDS. The application does not show treatment or prevention of any such disorder.

Additionally, whereas instant claim 1 is drawn to the inhibition of any immunodeficiency virus, the instant specification provides direction and guidance relating to one type of virus, HIV, and does not show or describe any other type of immunodeficiency virus which may also be susceptible to CDDO inhibition according the mechanism hypothesized: p21 inhibition. While retroviruses having life cycles and depending on proteins common to those in HIV might reasonably be enabled within the scope of the method, the Examiner finds no evidence in the specification or prior art to support the extrapolation to all known and yet to be identified immunodeficiency viruses. Rather, the direction and guidance is limited to HIV. The application to all other immunodeficiency viruses, whatever those may be, would appear speculative at best.

Additionally, while Applicant has shown that CDDO is biologically active against HIV and effectively reduce HIV replication, Applicant has not provide the direction or assurance necessary to enable one of skill to practice the methods using any CDDO derivative without having to resort to *de novo* trial and error experimentation to identify which, if any, CDDO derivative may be used as now claimed. Such experimentation, in the absence of any evidence of ever reaching a successful conclusion, is considered to be undue.

It is reasonable therefore to question whether sufficient direction and guidance has been provided to enable one of skill to practice the claims as broadly as now claimed.

Considering the breadth of the claims, the state of the art at the time of filing, the level of unpredictability in the art, and the limited guidance and working examples provided by the instant application, the Examiner submits that the skilled artisan would be required to conduct

undue, trial and error experimentation to practice the claimed invention commensurate with the claims scope.

Accordingly, the instant claims are rejected for failing to comply with the enablement requirement.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 2 are rejected under 35 U.S.C. 102(a) as being anticipated by Place et al. (July 2003) "The novel synthetic triterpenoid, CDDO-imidazolide, inhibits inflammatory response and tumor growth in vivo" *Clin. Cancer. Res.* 9(7): 2798-806.

*Claim interpretation:*

Claims 1 and 2 embrace a method of providing CDDO or any derivative of CDDO to any human cell in an amount sufficient to cause attenuation of immunodeficiency virus, such as HIV. The claims do not require the cell or individual containing the cell be infected with HIV. Indeed, as now written the claims read on any method of administering CDDO to any cell in vitro or in vivo for any purpose. The preamble of claim 1 is given no patentable weight, since the body of

the claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states the purpose or intended use of the invention (MPEP 2111.02). The intended purpose recited in the preamble is an effect inherent to the administration of CDDO to an individual or subject, as a compound and its properties are inseparable.

Claim 13 (not included in this rejection) is construed as being limited to individuals having AIDS.

Place et al. disclosed a method of administering various amounts, from 30 nM to 100 nm, CDDO and a derivative of CDDO (CDDO-Im) to human cancer cells in culture (Figs. 1 and 2). The administration of CDDO compounds is shown to suppress the proliferation of the human cancer cells. As the specification teaches that 0.1 μM CDDO is sufficient to produce effects similar to what is now claimed (Fig. 5, page 10 and 63), the amounts disclosed by Place et al. would appear to meet this limitation.

Accordingly, Place et al. disclosed a method within the scope of what is now claimed.

***

Claims 1, 2, and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Salcedo et al. (WO 2004/016753).

The claims do not exclude administration of compositions comprising CDDO or combination therapies comprising the use of CDDO in combination with any other anti-HIV agent.

Salcedo et al. disclosed a method for treating HIV and AIDS in an individual comprising administering antibodies that bind TRAIL receptor (TR4) together with 2-cyano-3,12-dioxooleana-1,9-dien-28-oic acid (CDDO) (paragraphs 477, 402, 404, 429).

Accordingly, Salcedo et al. disclosed a method within the scope of what is now claimed.

***

Claims 1, 2, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Xu et al. (US Patent 5,916,919) "Retrovirus protease inhibitors."

The claims read on methods of treating and/or inhibiting HIV infection, replication, or propagation in an individual by administering a derivative of CDDO.

Xu et al. claimed and disclosed a method of treating retroviral infection, such as HIV infection, comprising administering a triterpene compound, including any of those defined by Formula I (Fig. 11) or any of those described at columns 3-6. See also claims 1-6. The triterpenes disclosed are reasonably considered to be synthetic derivatives of CDDO. Xu et al. further taught that included within their invention are modified derivatives of the compounds of Formula I (col. 3, lines 30-35). One of skill would instantly recognize the method is intended for use in any HIV infected individual, including one with AIDS.

Accordingly, Sim et al. disclosed a method within the scope of what is now claimed.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xu et al. (US Patent 5,916,919) "Retrovirus protease inhibitors" in view of Salcedo et al. (WO 2004/016753) "Antibodies that immunospecifically bind to TRAIL receptors" and Nasti et al. (1997) "Malignant tumors and AIDS" *Biomed. Pharmacother.* 51:243-251.

Xu et al. is relied on for the reasons given above in the rejection of claims 1, 2, and 13 under 35 USC 102. It is further noted Xu et al. had, as a whole, taught that several different types of triterpenes inhibit retroviral protease, including the HIV protease, and that these compounds are therefore useful for treating HIV infection. See, for example, Summary of Invention, beginning at column 3, and Detailed Description of the Invention, beginning at column 4. It is further noted that CDDO, or 2-cyano-3,12-dioxoolean-1,9-dien-28-oic acid, is a triterpenoid (page 62-3 of the specification), and that the art refers to CDDO as both a triterpene and triterpenoid.

Xu et al. does not teach CDDO in particular.

Salcedo et al. is also relied on for the reasons given above in the rejection of claims 1, 2, and 13 under 35 USC 102. As explained above, Salcedo et al. had expressly suggested using a combination of CDDO and TRAIL receptor immunospecific antibodies for treating HIV infection and AIDS.

Accordingly, in view of Xu et al. and Salcedo et al. as a whole, one of skill would reasonably have concluded at the time of invention that CDDO, as well as other triterpenes, may be used alone or in combination with other therapeutic agents in the treatment of HIV infection in an individual, including an individual suffering from AIDS.

Additionally, and apart from the reasoning above, it is further noted Salcedo et al. had taught at paragraph 481 that antibodies of their invention may be administered in combination with one or more therapeutic agents, including CDDO (paragraph 476), in the treatment, prevention, amelioration and/or cure of Kaposi's sarcoma (see also paragraph 384).

The prior art had taught that, in western countries, Kaposi's sarcoma is over 2,000 times more common in HIV-infected individuals that in the general population, and that in certain AIDS populations, the prevalence of KS may be 21%. See, for example, Nasti et al. (1997) "Malignant tumors and AIDS" *Biomed. Pharmacother.* 51:243-251.

Accordingly, in view of Salcedo et al. one of skill would had reason to apply the antibody/CDDO combination therapy for to treat any of the cancers specifically recommended by Salcedo et al., including Kaposi's sarcoma. Given that Salcedo et al. make no exclusions as to the target population having KS, one of skill would reasonably have concluded this therapy may be used in any patient having KS, including HIV-infected patients suffering from KS. As a result one of skill following the suggestion of Salcedo et al., would have had reason to use the method

in HIV-infected patients, including AIDS patients, reasonably predicting the therapy would be effective for the treatment of KS in said patients, as taught by Salcedo et al.

Consequently, for this reason, too, the prior art had suggested a method within the scope of what is now claimed.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louis Wollenberger whose telephone number is (571)272-8144. The examiner can normally be reached on M-F, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tracy Vivlemore can be reached on (571)272-2914. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Louis Wollenberger/
Primary Examiner, Art Unit 1635
November 20, 2009